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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,458	02/11/2000	Michael R. Rosen	61020-A/HOW/PJP	6325

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Cooper & Dunham LLP
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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/01/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,458

Applicant(s)

ROSEN ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/1/8/03 (Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 4/18/03 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant has amended independent claims 1, 12, 20, 31, 39, 50, 58, 59 and 60 to include using the method/ device for treatment "to prevent or reverse arrhythmias". The Applicant has cited the specification to support these new limitations, specifically:

1) page 5, line 5 - "It is a further objective of the invention to provide an apparatus and method for pacing of the heart for sustained periods of time to induce remodeling of gap junctions and ion channels, to sustain an antiarrhythmic effect and alter contractile patterns as well.",

2) page 41, line 13 - relative to the activation-recovery intervals and effective refractory periods at the same sites, the remodeling “provides greater protection at each site from the propagation of premature depolarizations that had occurred previously, in other words, a profound antiarrhythmic effect.”

3) page 42, lines 12-15 - “the pacing invention performed is most likely to prevent it (the arrhythmia) from either expressing or sustaining itself.”

The Examiner finds these passages do not support the new limitation. These citations support “to prevent arrhythmias”, “to sustain an antiarrhythmic effect”, “to alter contractile patterns”, and “to provide an antiarrhythmic effect”, but they do not support “to reverse arrhythmias”. The phrase “to prevent or reverse arrhythmias” is viewed as new matter, and new matter may not be introduced at this point in the prosecution. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. Claims 1, 9-11, 20, 28-30, 39 and 47-49 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ben-Haim et al. (US 6363279) for the reasons of record.

Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field. The mechanical activation of the heart is controlled by electrical stimulation where action potentials from the S-A node enter the heart conduction system and propagate through the ventricles of the heart by sequentially activating connected muscle fibers (col. 1 @ 31-45). This invention focuses on controlling the heart by modifying the action potentials, the ionic pumps and the channels of the heart (col. 2 @ 6 – col. 3 @ 32).

This invention focuses on controlling the heart by modifying the channels that connect the heart; the channels are read to include gap junction channels (col. 2 @ 6 – col. 3 @ 32).

According the Ben-Haim et al., these channels of the heart are modified by electrical stimulation (col. 27 @ 12-27; col. 27 @ 52-57; col. 31 @ 1-5). While Ben-Haim addresses the controlling the channels of the heart, the gap junction channels are not specifically mentioned. It is however inherent that the Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the art made of record (Winslow et al. US 5947899, - col. 5 @ 28 – col. 6 @ 3; col. 6 @ 33-53).

Refractory periods are modified by electrical stimulation (col. 8 @ 3-5; col. 47 @ 37-45; col. 8 @ 66 – col. 9 @ 3; col. 9 @ 15-19; col. 17 @ 26-35; col. 17 @ 45-46; col. 31 @ 26-31).

Ion channels are modified by electrical stimulation (col. 26 @ 62 – col. 27 @ 27; col. 27 @ 43-57; col. 31 @ 1-5).

Changes in the heart occur over time as the heart is remodeled (col. 9 @ 51-55; col. 38 @ 48 – col. 39 @ 10). Electrodes can be attached by sewing (col. 30 @ 9-12). Electrodes can be placed in the heart or in vessels (col. 37 @ 30-35; col. 40 @ 48-51). Electrodes can be activated in pairs (col. 37 @ 15-17).

As to preventing arrhythmias, Ben Haim et al. disclose providing therapy to reduce the probability of ventricular fibrillation, read as preventing arrhythmias (col. 8 @ 44-48).

The Applicant's arguments filed 4/18/03 have been fully considered, but they are not convincing.

The Applicant appears to argue that the Examiner has misunderstood the meaning of the term "channels" used in Ben-Haim et al. (col. 2 @ 6 – col. 3 @ 32). The Applicant appears to assert a definition for "channel" as used by Ben-Haim et al., but the Applicant fails to provide

citations from Ben Haim et al. to convince the Examiner that the Applicant's interpretation of the term is correct. The Applicant states transmembrane channels are referred to as ion channels whereas the gap junction are referred to as connections, but the Examiner is unable to find this terminology in Ben Haim et al.. Lacking a convincing argument with citations, the rejections of record stand.

The Applicant argues the instant invention provides long-term remodeling and altering of the cardiac processes and Ben-Haim et al. only provides change and control of the cardiac processes in a current moment. The Applicant further asserts the Ben-Haim et al. method produces cardiac change only when the electrical stimulation is applied and the effect of the change ceases when electrical stimulation ceases. The Examiner disagrees. Ben-Haim et al. does apply stimulation to create cardiac process changes in the current moment. In addition, Ben-Haim et al. recognize applying electrical stimulation in the current moment produces long-term/ permanent changes of the cardiac processes, read as remodeling and altering of the cardiac processes. These long-term changes are reflected in a need for the therapy to be altered periodically and are reflected when treatment targets are met and the therapy is discontinued because the cardiac process has been changed to the point that therapy is no longer needed, hence Ben-Haim et al. disclose changes in the cardiac process in the moment and long-term (col. 9 @ 15-19; col. 9 @ 51 – col. 10 @ 3; col. 30 @ 34-37; col. 34 @ 15-38; col. 35 @ 55-59; col. 38 @ 48 – col. 39 @ 18).

The Applicant argues that since Ben-Haim et al. only changing the muscle mass of the heart over time, changing muscle mass does not necessarily result in remodeling the gap junction, altering the refractory period in the heart or inducing the ion channel remodeling.

The Examiner disagrees. Ben-Haim et al. disclose methods to control and change the electrical and mechanic activity of the cardiac muscle cells that produce changes the muscle mass and changes in the action potential plateau duration, the activation time, the activation sequence, the contractability and the conduction pathways of the cardiac segment, hence Ben-Haim is read to remodel gap junctions, alter the heart refractory period and induce ion channel remodeling (col. 2 @ 6 – col. 3 @ 32; col. 7 @ 65-67; col. 34 @ 28-34).

Claim Rejections - 35 USC § 103

5. Claims 2, 5, 12, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308) for the reasons of record.

As discussed in paragraph 4 of this action, Ben Haim et al. disclose the claimed invention except for the 7cm x 1 cm (claims 4, 23 and 42) strip (claims 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pairs are arranged in two columns (claims 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claims 5, 15, 24, 34, 43, 53 and 58-60).

Edwards et al. disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed to enable stimulation of electrode pairs (figure 7; col. 7 @ 38-52). Absent any teaching of criticality or unexpected results, it is understood the electrode can be configured as a 7cm x 1 cm strip with only two columns of electrodes. The configuration change is an obvious change in

shape based on the specific application. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

6. Claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (5681308) and further in view of Dahl et al. (US 5203348) for the reasons of record.

As discussed in paragraphs 4 and 5 of this action, modified Ben-Haim et al. disclose the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 17-18, 36-37 and 55-56), and
- the electrode connected to insulated stainless steel wire (claims 19, 38 and 57).

Dahl et al. disclose an electrode and teach that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (col. 5 @ 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (col. 5 @ 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the materials of construction as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a

modification in electrode to specify materials of construction that have proven electrical properties.

7. Claims 7, 8, 26, 27, 45 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348) for the reasons of record.

As discussed in paragraph 4 of this action, Ben-Haim et al. disclose the claimed invention except for the electrode being platinum or consisting essentially of unalloyed platinum.

Dahl et al. disclose an electrode and teach that it is known to fabricate an electrode with a platinum or platinum alloy conductor (col. 5 @ 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the platinum of platinum alloy conductor as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

8. Claims 6, 16, 25, 35, 44 and 54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308) and further in view of Ideker (US 5873896) for the reasons of record.

As discussed in paragraphs 4 and 5 of this action, modified Ben-Haim et al. disclose the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at least 5 mm apart.

Idecker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes

positioned at spaced intervals, e.g. 1-4 millimeters (col. 3 @ 2-4). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode spacing as taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythmias.

Specification

9. On page 40, line 23, it appears "duration" should be --duration--.

Information Disclosure Statement

10. One reference (an article by Katz) associated with the information disclosure statement (IDS) filed 4/18/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The IDS has been placed in the application file with a line through the Katz article; the Katz article has not been considered.

Amendment file 4/18/03

11. In the listing of the claims in the Amendment filed 4/1/8/03, claim 43 is not the claim 43 of record. It appears claim 39 was inadvertently duplicated and labeled as claim 43. Claim 43 is noted to be "currently amended" however the Examiner believes this is a mistake and the rejection in the previous paragraphs of this action reflects claim 39 not being amended. Clarification and amendment of claim 39 to reflect the "pre-4/18/03" claim 39 appears to be needed. Correction is required.

Statutory Basis

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

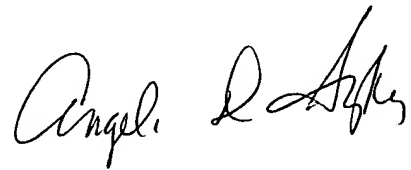
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
4/25/03



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